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Kimberlee Fisher 11/4/02
Kimberlee Fisher Date

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s): Howard Fein, M.D.
Application No.: 09/919,102
Filed: July 31, 2001
Art Unit: 1651
Confirmation No.: 2446
Examiner: Jean C. Witz
Title: **SELECTIVE ENZYME TREATMENT OF SKIN CONDITIONS**
Atty. Docket No.: HOFE-02

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TECH CENTER 1600/2900

Cincinnati, OH 45202

November 4, 2002

Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office Action mailed October 2, 2002 in the above-referenced application, applicant elects with traverse Group 1 (claims 1-10, 24-41), drawn to a method for treating a condition affecting at least one layer of the skin wherein the enzyme is trypsin.

However, applicant respectfully asserts that such a restriction is improper. Applicant has filed a Preliminary Amendment amending claims 1,2, 4-7, 9, 20, 21, 30, 34, 35, and 39-41 to recite a hydrolase. At the outset, applicant notes that amended claims 1-10 and 24-41 are now directed to methods for treating skin conditions with a composition that contains a hydrolase. Amended claims 11-20 (Group II) and amended claims 21-25 (Group III) are directed to a composition that contains various hydrolases, and claims to such compositions should not be restricted based on enzyme function. Applicant now provides the following analysis in support of his assertion regarding the impropriety of a species election.

First, the Examiner's restriction forces applicant to fragment the invention claimed within a single claim. Under *In re Weber, Soder, & Boksay*, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978) (copy attached) this is not permitted.

The invention in *Weber* related to cyclic diamine derivatives possessing a common psychotherapeutic property and was identified by a single generic formula expressed in Markush format. The instant invention relates to hydrolases, a class of transferases, possessing the common biochemical property of transferring a donor group to water. The hydrolases are expressed in Markush format; the selection of which hydrolase to use in the composition and method of treatment depends upon the layer or layers of skin to be treated.

In *Weber*, the court viewed the Examiner's restriction as tantamount to a refusal to examine. It held that the United States Patent and Trademark Office has the authority to restrict between claims of an application reciting one or more independent and

distinct inventions, but does not have the authority to require an applicant to divide up a single claim and present it in different applications; this would allow an Examiner, rather than an applicant, to define an invention in violation of 35 U.S.C. §121, ¶2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention", emphasis added). Weber at 332. While recognizing the need for efficiency in limiting each application to one invention, the court stated that

...in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights [of the applicant] are paramount.

Second, §803.02 of the MPEP states that if the claims have unity of invention, it is improper to refuse to examine "that which applicants regard as their invention". Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature as being essential to that utility.

With regard to the instant application, all of the method and composition claims as amended share a common class of enzyme, that is, the hydrolases, which have the same utility to transfer a donor group to water.

Applicant also respectfully disagrees with the Examiner's position that "in the instant case the method can be practiced with a materially different product such as an alpha-hydroxy acid." Alpha-hydroxy acids are conventionally used in over-the-counter cosmetics to cause nonspecific exfoliation or shedding of the skin surface. When these

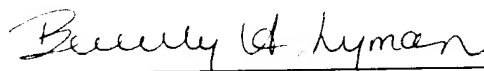
acids are used in higher concentrations than what is conventionally used in exfoliation cosmetics, they can cause nonspecific tissue damage such as the detachment of keratinocytes and epidermolysis. In applicant's instant applications, the hydrolases used in the composition and method produce selective tissue destruction limited to one or more layers of the skin that are involved with a certain skin condition.

For the reasons discussed, applicant respectfully requests that the Examiner reconsider the restriction requirement.

Applicant knows of no fee due with this submission, as November 2, 2002 was a Saturday. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account 23-3000.

Respectfully submitted,

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